



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

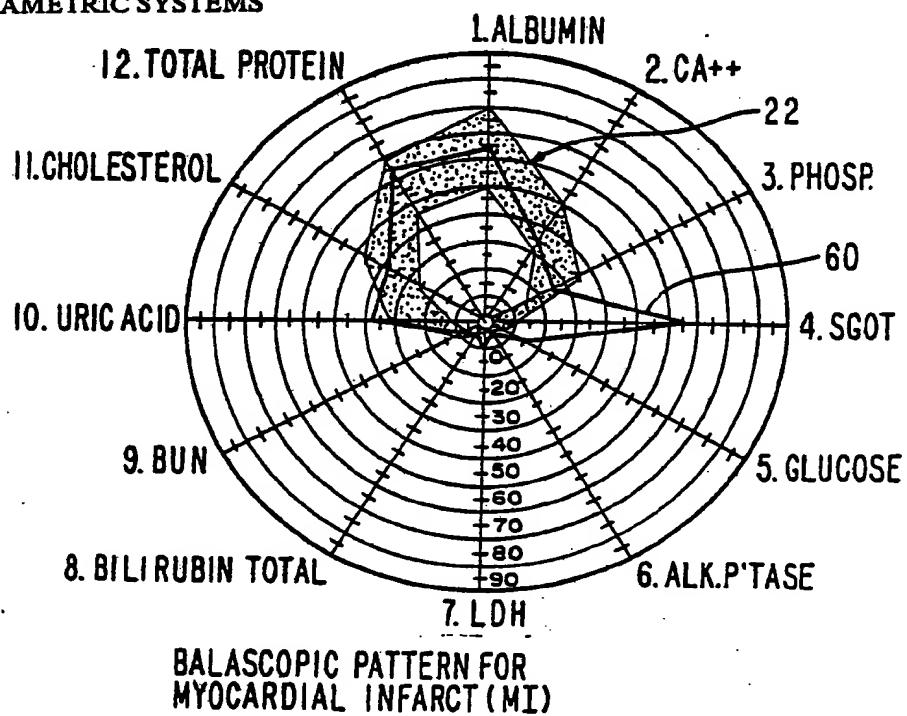
| | | |
|--|----|---|
| (51) International Patent Classification 3 : A61B 5/04; G06G 7/12 | A1 | (11) International Publication Number: WO 84/02458 (43) International Publication Date: 5 July 1984 (05.07.84) |
|--|----|---|

| | |
|---|--|
| (21) International Application Number: PCT/US83/01730 (22) International Filing Date: 3 November 1983 (03.11.83) (31) Priority Application Number: 454,196 (32) Priority Date: 29 December 1982 (29.12.82) (33) Priority Country: US (71)(72) Applicant and Inventor: KVITASH, Vadim, I. [Stateless/US]; 419 11th Avenue, San Francisco, CA 94118 (US). (74) Agent: PRESSMAN, David; 1237 Chestnut Street, San Francisco, CA 94109 (US). (81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), JP, LU (European patent), NL (European patent), SE (European patent). | Published <i>With international search report. With amended claims.</i> |
|---|--|

(54) Title: BALASCOPY: METHOD FOR DETECTING AND RAPIDLY EVALUATING MULTIPLE IMBALANCES WITHIN MULTI-PARAMETRIC SYSTEMS

(57) Abstract

In a system in which multiple related parameters, such blood chemistry data, are to be evaluated, such evaluation is facilitated by converting the data into specially normalized units as a percentage on a scale depicting the maximum and minimum empirical values for such parameter. Then a normal relationship between pairs of such data (Fig. 1--N) is provided and compared with measured relationships between corresponding pairs of data (Fig. 1--CN to FN) and quantitative and qualitative evaluations are made. Also the complete set of data for such a system is plotted on respective radial axes in such normalized units on a circular coordinate system with the respective maximum and minimum for each parameter being marked on its radius (Fig. 2). The maxima and minima are interconnected to form two closed lines (22), thereby to provide an annulus representing the normal range. Then measured parameters for various entities are similarly plotted and compared with the normal annulus or known abnormal annuli (Fig. 3 to 7). Also circular point diagrams are provided, with points on a circular path representing respective parameters and respective pairs of points being connected in cases where a normal quantitative relationship exists (Fig. 8A) or where a specified type of qualitative abnormal relationship exists (Figs. 8B to 8F), thereby to depict more readily the condition of the system. The data or parameters may be plotted with the aid of an EDP system (Fig. 9).





1
2
3
4
5
6
7
8
9

1

10

BALASCOPY : METHOD FOR DETECTING AND RAPIDLY EVALUATING MULTIPLE IMBALANCES WITHIN MULTI-PARAMETRIC SYSTEMS

14 Background--Field of Invention

15 The present invention relates to the detection and
16 evaluation of multiple imbalances within multi-parametric
17 systems, particularly to the employment of graphic means for
18 performing such detections and evaluations. It is
19 particularly useful in the field of medicine for the diagnosis
20 and follow-up treatment of diseases. It may be used in many
21 other fields for evaluating, diagnosing, predicting,
22 analyzing, describing behavior, change of behavior, etc.,
23 where multiple parameters in a related system are involved.

25 Background--Description of Prior Art

26 In medicine, for optimal care and therapy, quantitative
27 as well as qualitative judgments of the degrees of
28 abnormalities should be made when diagnosing patients.
29 Previous studies have suggested that an analysis of
30 combinations of laboratory data of a patient may be of greater
31 aid in understanding the patient's condition than an analysis
32 of individual items of data per se.

Heretofore one scientific method of diagnosing diseases from laboratory data has used a statistical analysis of deviations of a patient's data from a normal range. The results obtained were arranged in the form of a circular coordinate system which employed radial axes calibrated



1 according to the patient's laboratory parameters, with
2 standard deviations of each parameter plotted on the
3 respective axes. Following this, a pattern was created by
4 interconnecting adjacent points on the axes. Diagnosis was
5 performed by comparing the obtained pattern of an individual
6 patient with reference patterns typical for certain diseases.
7 J.H. Siegel, "Relations Between Circulatory and Metabolic
8 Changes in Sepsis," 32 Ann.Rev.Med. (Annual Reviews, Inc.
9 1981) 175-194; also see the "Patient Data System," General
10 Electric Medical Systems (adv't.), Critical Care Medicine,
11 Jan/Feb 1976.

12 While useful, these methods did not provide sufficient
13 information for one to detect pathology with normal data and
14 did not reveal qualitative and quantitative types of
15 imbalances between parameters.

16 Another method has been suggested in an attempt to
17 overcome these difficulties. This method was similar to the
18 previous ones: a circular type presentation of parameters on
19 radial axes was provided with values plotted on the radial
20 axes, but expressed as a percentage of normal values, rather
21 than by standard deviations. S. Nazari et al., "A
22 Multivariable Pattern for Nutritional Assessment," 4 J.
23 Parenteral and Enteral Nutrition 499, 1980.

24 This method provided more distinguishable patterns than
25 the previous one because the percentage scale was more
26 sensitive than the standard deviation scale. Nevertheless
27 this method still did not provide sufficient information for
28 one to obtain quantitative and qualitative types of imbalances
29 between parameters and did not reveal any multiple imbalances
30 which were present within the system.

31

32 Objects

Accordingly one object of the invention is to obviate the disadvantages inherent in existing modes of analyzing, diagnosing, and evaluating medical and other data. Another object is to provide a new method of evaluation based on quantitatively and qualitatively-determined types of



1 imbalances between measured parameters in a medical or other
2 system. Further objects and advantages will become apparent
3 from a consideration of the ensuing description and
4 accompanying drawings.

5

6 Drawings

7 Fig 1 is a diagram illustrating various types of
8 imbalances in two blood chemistry parameters according to a
9 method of the present invention.

10 Fig 2 is a circular diagram of a normal pattern of blood
11 chemistry parameters, made according to a method of the
12 present invention.

13 Figs 3 to 6 are circular diagrams of abnormal blood
14 chemistry patterns typical for various diseases, plotted
15 according to the invention and with normal pattern ranges being
16 superimposed thereon.

17 Fig 7 is a table showing the data for the parameter set
18 of Fig 6, compiled according to the invention.

19 Fig 8, parts A to F, shows dot and line diagrams designed
20 to vivify parametric relationships according to the invention.

21 Fig 9 is a block diagram of an EDP system which may be
22 employed in the practice of the invention.

23

24 Description--Medical Use of Invention

25 Generally, laboratory data or measured parameters of a
26 patient are used to make and confirm a diagnosis and to
27 monitor the course of treatment. In a basic aspect of the
28 present invention, each measured parameter of a patient is
29 noted and is made far more useful and meaningful by expressing
30 it as a percentage between the minimum and maximum empirical
31 values of said parameter.

32 For example, the empirically existing maximum of the
total serum protein in vivo comprises 11.0 milligrams (mg) of
protein per tenth liter (deciliter--dl) of blood, and the
minimum is 2.0 mg/dl. The range between these values is thus
 $11.0 - 2.0 = 9.0$ mg/dl. This range is then converted into
special normalized units on a scale of 100, such that each

1 normalized unit will correspond to $100/9 = 11.1$ actual units
2 (in mg/dl). A patient's measured total serum protein value
3 may be thus converted to normalized units by subtracting the
4 minimum actual value from the patient's actual value and then
5 multiplying the result by 11.1 or by $100/9$.

6 Example 1: For example, if a patient's measured total
7 serum protein is 7.3 mg/dl, this value is made the minuend,
8 the minimum empirical value (2.0 mg/dl), is made the
9 subtrahend, and the difference, 5.3 mg/dl, is determined.
10 This difference (5.3 mg/dl) is then multiplied by the
11 normalized unit value, 11.1, to provide a special normalized
12 value according to the invention, which is 58.9 units.

13 I have designated these special normalized units
14 (regardless of the parameter represented) by the term
15 Balascopic[™] units [bala > balanced, and scopic > see] and they
16 will be so referred to hereinafter for ease of discussion. I
17 have designated my process Balascopy[™].

18

19 Fig 1--Use of Balascopic Units to Portray Relationships

20 Fig 1 shows how Balascopic units can be used to express
21 relationships between measured parameters of a patient in more
22 meaningful terms.

23 In Fig 1 the vertical scale is calibrated in Balascopic
24 units (BU) from 0 to 100, with 0 BU corresponding to the
25 existing empirical minimum and 100 BU corresponding to the
26 existing empirical maximum of both total serum protein and
27 serum albumin of a patient. The first (leftmost) block of
28 this diagram (labeled Normal and N) shows how Balascopic units
29 can be used to represent a normal relationship between these
30 two blood parameters. In this block, point P_N represents a
31 normal value of total serum protein in a patient. The
32 absolute value of Example 1 when converted from mg/dl—not
indicated—to Balascopic units, gives 58.9 or 59 BU, as
explained.

Assume further that the normal patient's serum albumin is
measured in an absolute measurement (not indicated) and when
converted to Balascopic units (according to the above-



1 described method), is 70 BU. This parameter is indicated at
2 point A_N .

3 A broken line is drawn to connect points P_N and A_N ; this
4 line indicates the normal relationship between these two
5 parameters. A normal differential (sometimes called
6 "gradient") between total serum protein (P_N) and serum albumin
7 (A_N) is thus equal to $70 \text{ BU} - 59 \text{ BU} = 11 \text{ BU}$. Preferably block
8 N is made of transparent material so that it can be
9 superimposed over any other block in Fig 1.

10 In Fig 1, the second block from the left, CN, illustrates
11 a deviation from the normal relationship between total serum
12 protein and serum albumin. In this case the values are Closer
13 than Normal (CN); this closer than normal relationship is
14 sometimes called an "integrated" relationship. According to
15 the previous procedure, the two values are measured, converted
16 to BU, and the resultant points are connected. The resultant
17 differential between them is assumed equal to 5 BU, i.e., less
18 than the normal differential (Block N) of 11 BU.

19 Since the two values P and A in blocks N and CN are
20 plotted the same distance apart, the gradients of their
21 interconnection lines can be easily compared by a
22 superimposition of the normal gradient upon the actual
23 measured gradient in block CN. The abnormality of the patient
24 in block CN can easily be seen by the reduced slope of the
25 solid gradient line $P_{CN} - A_{CN}$ in this block when compared with
26 the normal gradient (broken line $P_N - A_N$).

27 Similarly a type of imbalance where the two parameters
28 are too far apart is shown in the next block, FN (Further than
29 Normal). Here the Balascopic differential is equal to 40 BU,
30 which is farther than the normal 11 BU differential. This
31 "FN" (sometimes called "disintegrated") relationship can
32 easily be seen by the increased slope of the interconnection
line $P_{FN} - A_{FN}$, especially when compared with the superimposed
normal gradient (broken line $P_N - A_N$) superimposed thereover.

33 In the next block (NI) line $P_{NI} - A_{NI}$ has a normal
34 Balascopic gradient of 11 BU, but the mutual positions of the
35 two points are inverted from normal. This type of

1 relationship is called Normal Inverted (NI) and also is
2 vividly demarcated by the superimposed broken line P_N--A_N .

3 In the next block CI (Closer and Inverted) (sometimes
4 called "integrated" and inverted), line $P_{CI}--A_{CI}$ represents a
5 closer than normal and inverted relationship with a Balascopic
6 gradient of 10 BU. Compare this line with the normal broken
7 line P_N--A_N . In the last block, FI, a Farther than Normal and
8 at the same time inverted relationship is shown by the line
9 $P_{FI}--A_{FI}$. This farther than normal and inverted (sometimes
10 called "disintegrated" and inverted) relationship is also
11 vividly demarcated by the superimposed normal broken line P_N--
12 A_N .

13 As will be recognized by those skilled in the art, the
14 above method reveals five new definitive and qualitative types
15 of imbalances between blood chemistry parameters that can
16 be established. This method can also be used for any given
17 pair of parameters in a system of related parametric
18 quantities. Each of the above imbalances can be
19 quantitatively estimated by the degree of imbalance in
20 percent.

21

22 Fig 2--Simultaneous Comparison of Several Parameters for
23 Normal Patient

24 The relationships between many parameters in a system or
25 related parameters can be represented simultaneously by the
26 method illustrated by the diagram of Fig 2. Fig 2 shows a
27 circular coordinate system having twelve radial lines
28 corresponding to twelve standard blood chemistry parameters,
29 1. albumin, 2. Ca^{++} (Calcium ions), 3. phosphorous,
30 4. SGOT (serum glutamic oxytransaminase), 5. glucose,
31 6. alkaline, 7. phosphatase (alk. p'tase), 7. LDH (lactic
32 dehydrogenase), 8. bilirubin total, 9. BUN (blood urea
nitrogen), 10. uric acid, 11. cholesterol, and 12. total
protein. The reference or normal range for these parameters
are plotted in normalized or Balascopic units (BU) on the
respective axes in the manner aforescribed. The mean values
of these parameters are then interconnected to form a closed



1 or endless line 20.

2 The shaded ring-shaped or annular area 22 in Fig 2 shows
3 the normal range for a healthy population chosen by
4 conventional statistical methods. Area 22 is drawn by
5 plotting the normal lowest and highest values for each
6 parameter on its radial axis, and then interconnecting the
7 lowest points and the highest points to form two closed lines
8 (similar to line 22) and shading the area between these lines.
9 Note that the parameters connected by line 20 all fall within
10 the normal range. In order to simplify the visual comparison
11 and present it in a more obvious way, the radial axes on the
12 circular diagrams of Figs 2-6 are arranged in the specific
13 order indicated (rather than the standard sequence of a
14 laboratory test routine) so that the boundaries limiting the
15 normal range will define the substantially annular pattern
16 shown. If the axes were arranged in an order corresponding to
17 the sequence of a standard laboratory test routine, the
18 pattern of the normal range would have been too complicated
19 for comparison and too difficult to employ as an effective and
20 in diagnosis.

21

22 Figs 3 to 6--Simultaneous Comparison for Various Pathological
Conditions

23

24 Figs 3 to 6 are similar circular diagrams depicting
25 abnormal patterns of blood chemistry typical for the various
26 diseases indicated. In each of these figures, the
27 corresponding normal (shaded) range pattern 22 is superimposed
28 on the patient's annular blood chemistry plotted line.

29

30 In Fig 3, the blood chemistry for a patient with diabetes
31 mellitus with Kimmelstiel-Wilson disease and secondary
32 hyperparathyroidism is plotted as line 30.

31

32 In Fig 4, the blood chemistry for a patient with myxedema
is plotted.

In Fig 5, the blood chemistry for a patient with
thyrotoxicosis is plotted.

It can be seen that the use of a circular diagram with
the normal range for the blood chemistry parameters plotted
as a shaded ring and the patient's parameters plotted

1 thereover or thereunder by a solid line greatly facilitates,
 2 strengthens, and improves diagnosis, especially when prototype
 3 patterns for typical diseases (such as shown in Figs 3 to 6)
 4 are superimposed on the diagram, either with (not shown), or
 5 in lieu of the normal annular shaded area of Fig 2.
 6

7 Example 2--Fig 7

8 It is now possible and desirable to obtain a full set of
 9 the existing relationships between all parameters of blood
 10 chemistry expressed in terms of Balascopic differences or
 11 gradients. Skipping Fig 6 temporarily, this can be seen in
 12 Fig 7, where the blood chemistry data from a recently measured
 13 patient with a myocardial infarction (MI) and their
 14 corresponding values in Balascopic units (BU) are presented
 15 and taken from Table 1 below.
 16

| <u>Parameter Nr.</u> | <u>Parameter</u> | <u>Actual Value</u> | <u>Units</u> | <u>BU</u> |
|----------------------|------------------|---------------------|--------------|-----------|
| 1 | Albumin | 4.2 | mg/dl | 64 |
| 2 | CA ⁺⁺ | 8.8 | mg/dl | 35 |
| 3 | Phosphorous | 3.6 | mg/dl | 26 |
| 4 | SGOT | 330 | U/l | 66 |
| 5 | Glucose | 183 | mg/dl | 14 |
| 6 | Alk. P'tase | 84 | U/l | 6 |
| 7 | LDH | 665 | U/l | 13 |
| 8 | T. Bilirubin | .6 | mg/dl | 4 |
| 9 | BUN | 15 | mg/dl | 9 |
| 10 | Uric Acid | 84 | mg/dl | 39 |
| 11 | Cholesterol | 218 | mg/dl | 37 |
| 12 | Total Protein | 7.1 | mg/dl | 57 |

32 TABLE 1--BLOOD CHEMISTRY FROM PATIENT WITH MI

33 By way of example, consider the first line of Table 1
 34 which shows how this patient's albumin, measured as 4.2 mg/dl,
 35 is converted to Balascopic units (BU). The lowest value of
 36 albumin measured in a living patient is 1.0 mg/dl. The
 37 highest value is 6.0 mg/dl. According to the principle of
 38 Balascopy, the difference between these maximum and minimum is

1 taken to be 100 BU. To convert the patient's actual value of
2 4.2 mg/dl into BU, subtract the existing minimum (1.0) from
3 the actual value (4.2), multiply the result by 100, divide by
4 the difference between the existing maximum and the existing
5 minimum (5.0) to obtain the value indicated in the rightmost
6 column, 64 BU.

7 The other blood parameters for this patient have also
8 been processed in this manner to obtain the data in the "BU"
9 column. This patient's blood chemistry parameters are also
10 presented as line 60 in the radial chart of Fig 6, with the
11 shaded area 22 again representing the normal range and line 60
12 representing the patient's parameter's in BU, superimposed
13 over the "normal" annulus.

14 Note that Table 1 above presents relatively little
15 readily-understandable information and is difficult to analyze
16 or evaluate, either initially, or on a follow-up monitoring,
17 while the chart of Fig 6 presents a readily-identifiable
18 portrayal of this patient's pathology.
19

20 Fig 7--Parametric Quantitative, and Qualitative Relation-
21 ships--M1 OR FIG 6

22 While Fig 6 vividly depicts the patient's quantitative
23 relationships, the chart of Fig 7 shows the entire spectrum of
24 all existing parametric relationships in quantitative as well
25 as qualitative terms, and also indicates the actual and
26 Balascopic units for each parameter. For example in the
27 parameter row (third row down, just above double line)
28 parameter 1 has an actual value (second row down) of 4.2 mg/dl
29 and a value in BU (top row) of 64 units. The parameters are
30 also indicated by number in the rightmost column, to the right
31 of the double line.

32 The qualitative relationship of parameter 1 (rightmost
column) with parameter 10 (third row down) is indicated to be
closer than normal by the legend "CN" in the block at the
intersection of parameters 1 and 10 and this relationship
quantitatively is a 22 percent imbalance (same block).

These qualitative and quantitative relationships can be
determined as follows: The Balascopic difference between



1 parameter 1 (64 BU) and parameter 10 (39 BU) is $64 - 39 = 25$
2 BU. The average Balascopic difference between these two
3 parameters for the healthy population is 48.2 BU, with a
4 standard deviation (SD) of 8.1 BU. Thus the Balascopic
5 difference for a normal relationship (about 95% of the
6 population) should lie between the limits of the average value
7 ("X") ± 2 SD. Since X is 48.2 BU, this range extends for 48.2
8 $\pm (2 \times 8.1)$ BU or 32.0 to 64 BU. This means that any value of
9 Balascopic difference for a patient's parameters 1 and 10
10 between 32.0 and 64.4 BU can be considered a normal
11 relationship.

12 In the present example, the Balascopic difference is only
13 25 BU, which is less than 32.0 BU and therefore is an
14 imbalance type of relationship, a CN (Closer
15 than Normal) type because the difference (25 BU) is less than
16 the normal difference.

17 To evaluate the quantitative degree of closeness,
18 consider the range between the lower limit of the normal
19 difference (32 BU) and the maximum closeness (0 BU) as 100%
20 and determine the degree of actual closeness in percent.

21 In the present case the lower limit of normal difference
22 (32 BU) less the actual difference (25 BU) divided by the
23 lower limit (32) times 100 = 22 percent, as indicated in Fig 7
24 in the block at the intersection of parameters 1 and 10.

25 To take another example, the Balascopic gradient between
26 parameter 4 (66 BU) and parameter 7 (13 BU) is 53 BU. The
27 average Balascopic gradient between parameters 4 and 7 for a
28 healthy population is 1.3 BU, with the SD being 1.4 BU. Thus
29 the Balascopic gradient for a normal relationship should lie
30 between the limits of 1.3 ± 2.8 BU, or -1.8 BU to +4.5 BU.
31 However, because negative values are meaningless, the lower
32 limit is raised to zero and the normal range is considered
from 0 to 4.5 BU. In the present case, the differential of 53
BU far exceeds the normal range, i.e., is a farther than
normal (PN) type of imbalance. The degree of imbalance or
farness is equal to the given differential less the upper
limit of the normal differential times 100% divided by the

1 difference between 100 BU and the upper limit of the normal
 2 differential or $48.5 \text{ BU} \times 100\% = 95.5 \text{ BU} = 51\%$.

3 The formulae above used are valid for all of the abnormal
 4 qualitative relationships indicated in Fig 1 (CN, FN, CI, and
 5 FI).

6 The following Table 2 is a statistical analysis of the
 7 data in Table 1 and Fig 7. This table shows, for the 66
 8 existing pairs of relationships of the 12 blood parameters
 9 used, the actual number of occurrences of each type of
 10 relationship, the percentage of the total for each type of
 11 relationship, the statistical mean, in BU, of each type of
 12 relationship, and the statistical coefficient of variation for
 13 each relationship.

14

| Type of Relationship | Occurrences | Percent of Total Occurrences | Mean in BU | Coefficient of Variation |
|----------------------|-------------|------------------------------|------------|--------------------------|
| N | 33 | 50 | - | - |
| NI | 8 | 12 | - | - |
| CN | 9 | 14 | 13.55 | 70 |
| FN | 9 | 14 | 21.00 | 125 |
| CI | 3 | 5 | 65.33 | 61 |
| FI | 4 | 6 | 29.75 | 83 |

22

23 TABLE 2--Statistical Analysis of Relationships of Fig 7 and
Table 1

24

25 As will be appreciated by those skilled in the art it is
 26 difficult to draw a conclusion from data presented in the above
 27 tabulation, but by processing the data and presenting it in the
 28 form of the analytical graphs according to the invention with
 29 superimposed normal or known condition range values, a far
 30 clearer picture of pathology is readily presented.

31

32 Fig 8--Circular Point and Line Diagrams--MI of Figs 6 & 7

Fig 8 presents another method of graphically portraying the relationships and more vividly indicating the degree of abnormality. Fig 8 is divided into six parts, Figs 8A to 8F, respectively showing the six types of metabolic relationships (N, CN, FN, NI, CI, and FI), as discussed for the patient with the

1 myocardial infarct whose data are presented in the foregoing
2 tables and in Figs 6 and 7.

3 Each part of Fig 8 has 12 dots, numbered 1 to 12, spaced
4 evenly in a circular configuration, each dot representing one of
5 the 12 blood chemistry parameters aforesdiscussed. In each part
6 of Fig 8, every pair of parameters which have the metabolic
7 relationship specified by the heading of the part is indicated by
8 a line interconnecting the pair of dots representing the
9 parameters which have such a metabolic relationship. Thus in Fig
10 8A, the dots for every pair relationship which have a normal
11 relationship, i.e., the relative values of the parameters are in
12 the normal relationship range, are interconnected by a line. In
13 the patient under consideration, the relative values for the
14 following parameters are in the normal range and hence the
15 following pairs of dots are joined in Fig 8A: 1-2, 1-3, 1-6, 1-
16 8, 1-9, 1-11, 1-12, 2-3, 2-8, 2-9, 2-12, 3-5, 3-6, 3-8, 3-9, 3-
17 11, 3-12, 5-7, 5-10, 5-11, 5-12, 6-8, 6-9, 6-11, 6-12, 7-10, 7-
18 11, 8-9, 8-11, 8-12, 9-11, 9-12, and 11-12.

19 Since 50% of all existing pairs of parameters are joined in
20 Fig 8A, this is indicated by the legend "N: 50%" meaning that 50%
21 of the parametric relationships for this patient are normal.
22 Obviously the more lines that are present in a "normal" diagram
23 (Fig 8A), the better the patient's blood chemistry condition.

24 In Fig 8B, on the other hand, lines are shown for only the
25 parametric relationships which are abnormal in the normal but
26 inverted (NI) manner. Since this a pathological condition,
27 obviously the more lines which are present in Fig 8B (as well as
28 Figs 8C to 8F), the worse the patient's condition. As indicated
29 in Fig 8B, 12% of the patient's blood chemistry parametric
30 relationships are normal-inverted (NI).

31 The remaining four sections, C, D, E, and F, of Fig 8
32 represent the CN, CI, FN, and FI abnormal relationships and the
percentages of each of thse abnormal of these abnormal
relationships is indicated. In each of these sections, the mean
degree of abnormality (in BU) of the represented abnormal
parameter is also indicated, as is the statistical coefficient of
variation (CV) of such abnormal parameters. (No mean or CV is

1 indicated in Figs 8A or 8B because these sections represent
2 parametric relationships with quantitatively normal values).

3 It will be appreciated that the charts of Fig 8 will present
4 significantly more assimilable information to a trained person
5 than numerical data alone, or prior art charts. Also follow up
6 evaluation is greatly facilitated by comparing charts for a
7 patient at sequential stages of a disease.

8

9 Fig--10 Use of EDP System

10 Although foregoing charts and tables of the invention can be
11 assembled and plotted manually, preferably they should be done by
12 an electronic data processing system to eliminate manual labor,
13 eliminate errors, and speed evaluation. A system such as that
14 shown in Fig 9 would be suitable. The system comprises an input
15 unit (IU), such as a keyboard, cardreader, or the like, a central
16 processing unit (CPU) which includes a Read And write Memory
17 (RAM) and software; a Balascopic scale creator (BSC), which
18 serves to convert laboratory data from standard units to
19 Balascopic units (BU); a first resolver units (R1) which
20 determines quantitative criteria for normal relationships and for
21 each type of abnormal relationship; a second resloving unit (R2)
22 which develops quantitative parameters of the degree of imbalance
23 for each type of imbalance; a circular scale plotter (CSP) which
24 creates circular diagrams with radial axes corresponding to the
25 respective laboratory data parameters and which plots the data in
26 Balascopic or any other units on said axes; a visual display unit
27 (VDU); and an optional graphical printout unit (GPU) and
28 tabulator printout unit (TPU). The units preferably are
29 connected as indicated but alternatively, for versatility, all
30 units can be connected directly to and from the CPU. All of the
31 units of Fig 9 are available in the art and the programming can
32 be readily done by an experienced programmer.

The system of Fig 9 operates in the following manner: Laboratory data for a patient are inputed from the IU to the CPU and stored in its RAM. Then, under program control, the data are sent to the BSC which converts them into BU and supplies the converted data to the CSP for creating circular diagrams with

1 data plotted in BU on the proper axes. (Alternatively the data
2 from the BSC can be fed to R1 and from R1 to the CPU, CSP, VD,
3 GPU, or TPU.). The output of R1 is connected to R2, the latter
4 supplying output information to the the CPU and to the VDU, GPU,
5 and TPU.)

6 The above described system allows one to obtain new and
7 useful presentations of information which can be used for
8 diagnosis, monitoring, and control of treatment of various
9 diseases.

10

11

12

13 While the above description contains many specificities,
14 they should not be construed as limitations of the scope of the
15 invention, but rather as examples of several preferred
16 embodiments thereof. Various other embodiments and ramifications
17 are possible within its scope. For example instead of blood
18 chemistry, data other types of medical data, in any multi-
19 parametric system, such hematological data, neurological data,
20 dietic data, coronary data, etc., can be converted to BU and
charted. In addition to medicine, the invention can be used in
22 other field where multiple related parameters are found, such as
23 corporate security evaluation, competitive sports analysis and
24 prediction, etc. Accordingly the full scope of the invention
25 should be determined not be the examples given, but by the
26 appended claims and their legal equivalents.

27

28

29

30

31

32

1 Claims

2 I claim

3 1. A method of evaluating data in a multi-parametric system
4 comprising the steps of:

5 obtaining parametric data of such system;

6 converting each datum obtained into specially
7 normalized units by calculating the percentage of each
8 parameter within a range between two existing extreme values
9 of said parameter;10 providing a circular coordinate scale having radial
11 axes corresponding to said respective parameters of such
12 system and calibrated in such specially normalized units;13 plotting said specially normalized unit values of said
14 data as points on their respective axes on such circular
15 coordinate scale;16 creating a pattern by interconnecting adjacent points
17 on said radial axes to form a closed configuration pattern;
18 and19 evaluating said multi-parametric system by comparing
20 said closed configuration pattern with at least one
21 reference pattern plotted on a similar circular coordinate
22 scale and representative of a known state in said system.23 2. The method of claim 1 wherein said radial axes are
24 calibrated such that the boundaries limiting a normal range
25 define substantially an annular pattern.26 3. The method of claim 1 wherein said reference pattern is
27 formed on a scale identical to that of said scale in which the
28 normalized units are formed and said evaluating comprises
29 overlaying said normal pattern upon said pattern from obtained
30 data.31 4. A method of analyzing and evaluating a multi-parametric
32 system comprising the steps of:33 obtaining a plurality of related parameters of such
34 system;35 converting each parameter obtained into normalized
36 units by calculating a percentage of each parameter within a
37 range between two existing extreme values of said parameter;

1 comparing the quantitative values of all possible
2 combinations of said parameters in said normalized units;

3 determining the qualitative relationship of each
4 combination of said parameters by comparision of their
5 mutual values and said normalized units with corresponding
6 known mutual values of said parameters;

7 measuring the degree of differential deviation in said
8 normalized units for each pair of parameters from a
9 statistical average differential corresponding to each pair;
10 and

11 analyzing said system by comparing said deviations and
12 qualitative relationships with at least one reference
13 deviation typical for a known condition in said system.

14 5. The method of claim 4 wherein said related parameters
15 are medical laboratory data of a patient and said analyzing
16 comprises the diagnosing disease of such patient by comparing
17 said deviations and qualitative relationships with a known
18 deviation and qualitiative relationship of a known disease.

19 6. The method of claim 4 wherein said analyzing of said
20 system comprises plotting a diagram in which each of said
21 parameters is assigned a point at a respective location on said
22 diagram and interconnecting all pairs of points on said diagram
23 which represent a respective pair of parameters which have a
24 qualitative relationship which falls within a predetermined value
25 range.

26 7. The system of claim 4 wherein said analyzing of said
27 system comprises plotting a diagram in which each of said
28 parameters is assigned a point at a respective location on said
29 diagram and interconnecting all pairs of points on said diagram
30 which represent a respective pair of parameters which have a
31 qualitative relationship which falls outside of a predetermined
32 value range.

 8. A system for diagnosis, monitoring and control of
 effectiveness of treatment comprising:

 an input device, a central processing unit with memory,
 a normalized scale creator for converting laboratory data
 from standard units into normalized units, said normalized



1 scale creator being connected to said central processing
2 unit;

3 a first resolving unit for determining quantitative
4 criteria for normal relationships and for each type of
5 abnormal relationship, said unit being connected to said
6 central processing unit and said normalized scale creator;

7 a second resolving unit which develops quantitative
8 parameters of degree of imbalance for each type of
9 imbalance, said second resolving unit being connected to
10 said central processing unit and said first resolving unit;

11 a circular scale plotter which creates circular
12 diagrams with a number of radial axes corresponding to said
13 laboratory data parameters and which plots the data in
14 normalized units on said axes, said circular scale plotter
15 being connected to said normalized scale creator and said
16 first resolving unit;

17 a visual display unit which selectively displays data
18 from said circular scale plotter, said first resolving unit
19 and said second resolving unit;

20 said visual display unit being connected to said last-
21 named three units;

22 a unit for printing in graphical form data supplied
23 thereto, said printout unit being connected to said circular
24 scale plotter and said first and second resolving units; and

25 a unit for printing out data in tabular form, said
26 tabular form printout unit being connected to said resolving
27 unit.

28

29

30

31

32

AMENDED CLAIMS

[received by the International Bureau on 16 April 1984 (16.04.84);
original claims 2,3,5,6,7,8 unchanged; claims 1 and 4 amended]

1. A method of evaluating data in a multi-parametric system, comprising the steps of:

obtaining a plurality of parametric data of such system;

converting each datum obtained to a specially-normalized unit value equal to the percentage of the value of each parameter within the range between two existing and previously-determined extreme values of said parameter;

providing a circular coordinate scale having radial axes corresponding to said respective parameters of such system, each axis being identically calibrated in said specially-normalized unit values;

plotting said specially-normalized unit values of said data as points on their respective axes of said circular coordinate scale;

creating a pattern by interconnecting adjacent points on said radial axes to form a closed configuration pattern; and

evaluating said multi-parametric system by comparing said closed configuration pattern with at least one reference pattern plotted on a similar circular coordinate scale and representative of a known state in said system.

2. The method of claim 1 wherein said radial axes are calibrated and arranged such that the boundaries limiting a normal range define substantially an annular pattern.

3. The method of claim 1 wherein said reference pattern is formed on a scale identical to that of said scale in which the normalized units are formed and said evaluating comprises overlaying said normal pattern upon said pattern from obtained data.

4. A method of analyzing and evaluating a multi-parametric system, comprising the steps of:

obtaining a plurality of related parameters of such system;

converting each parameter obtained into normalized units by calculating the percentage of each parameter within the range between two existing extreme values of said parameter;



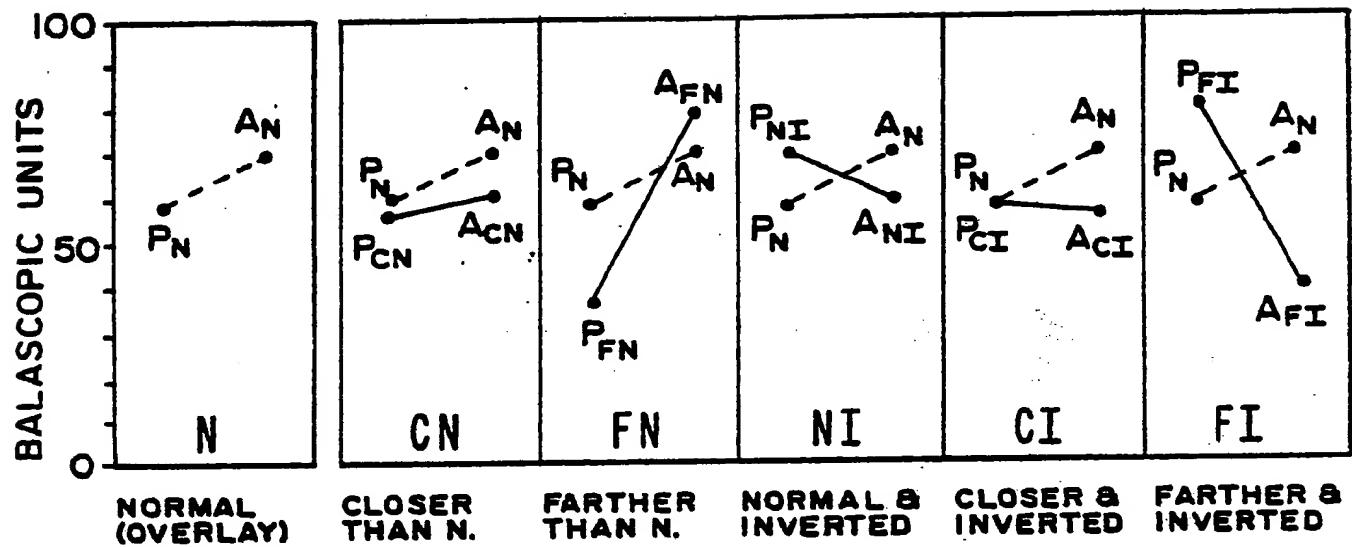
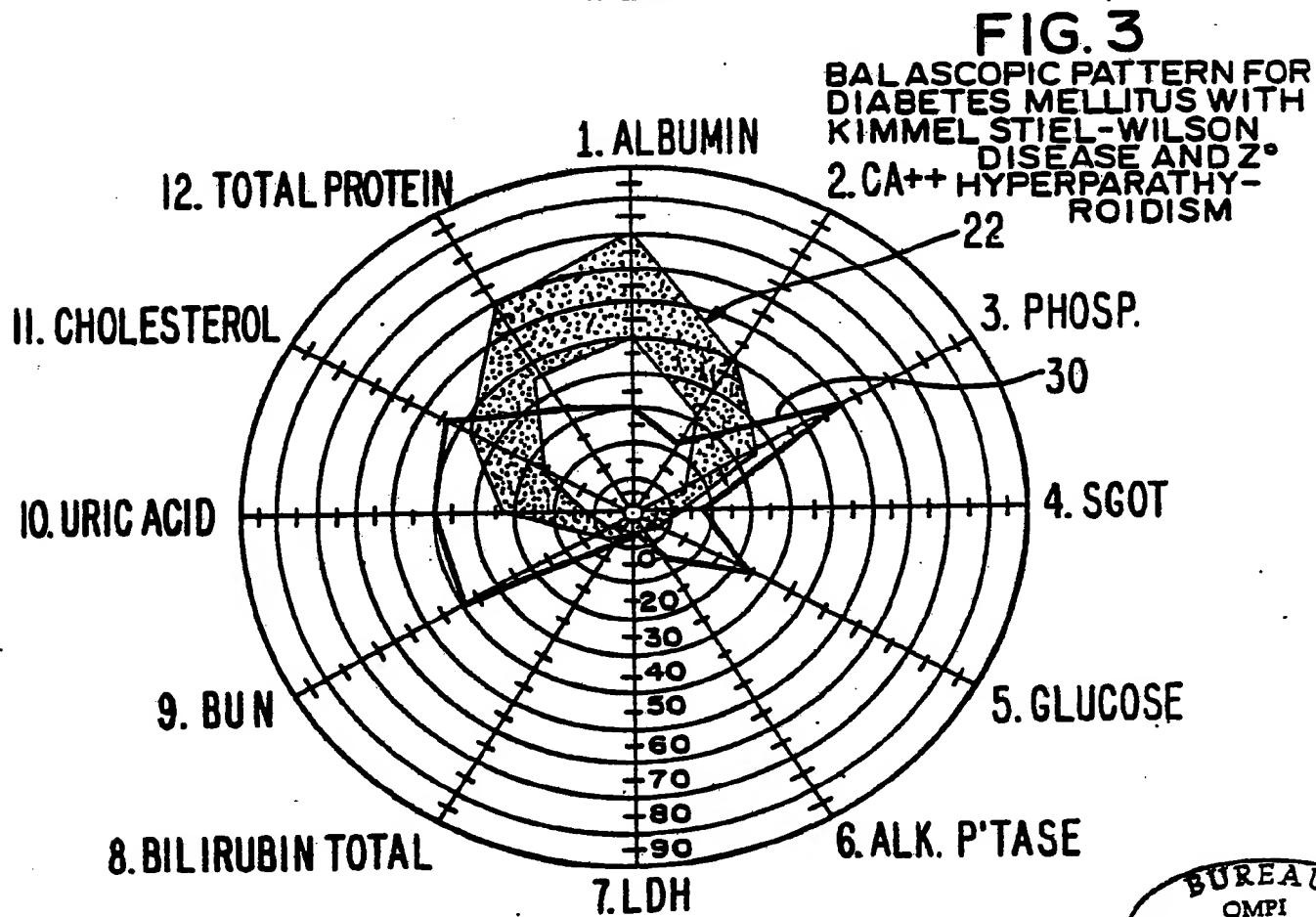
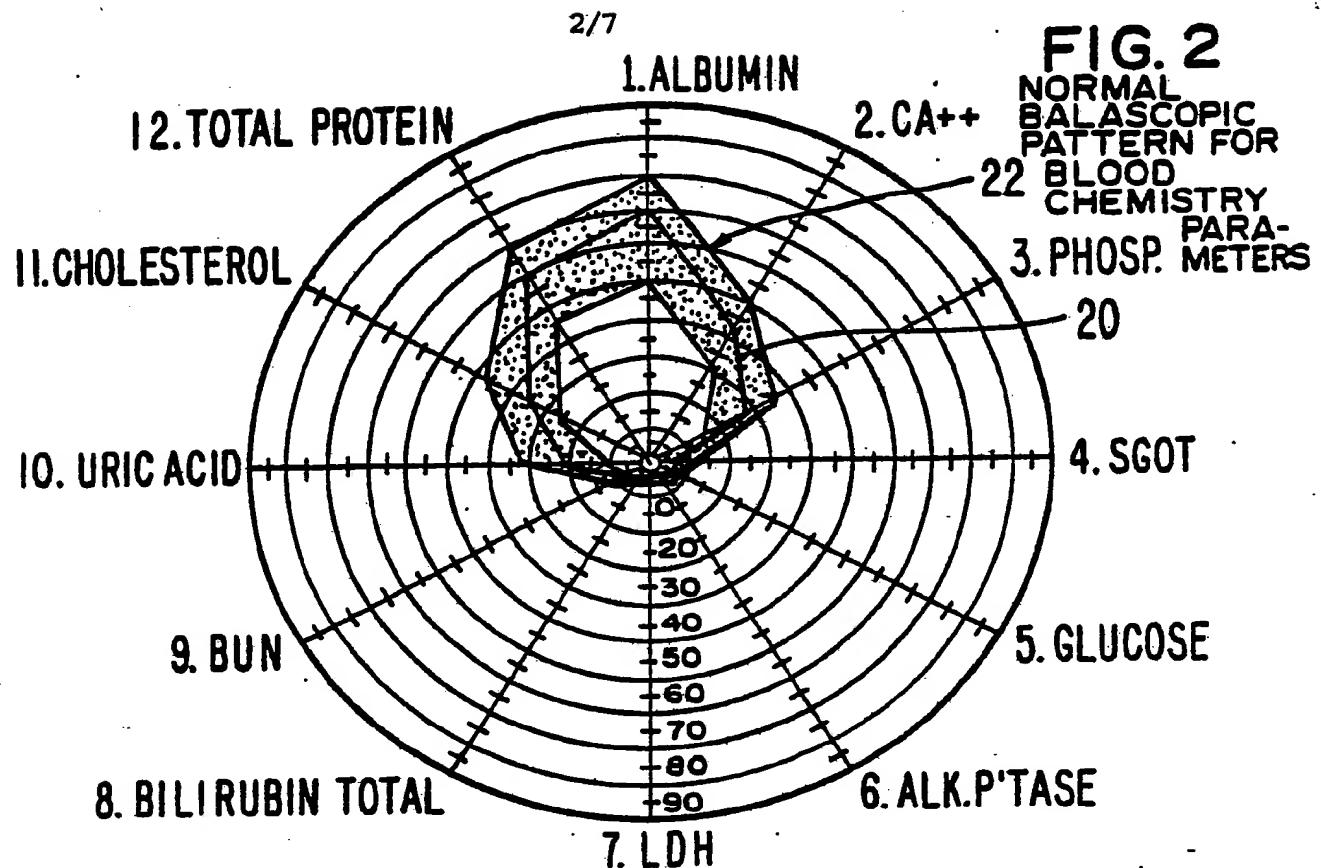
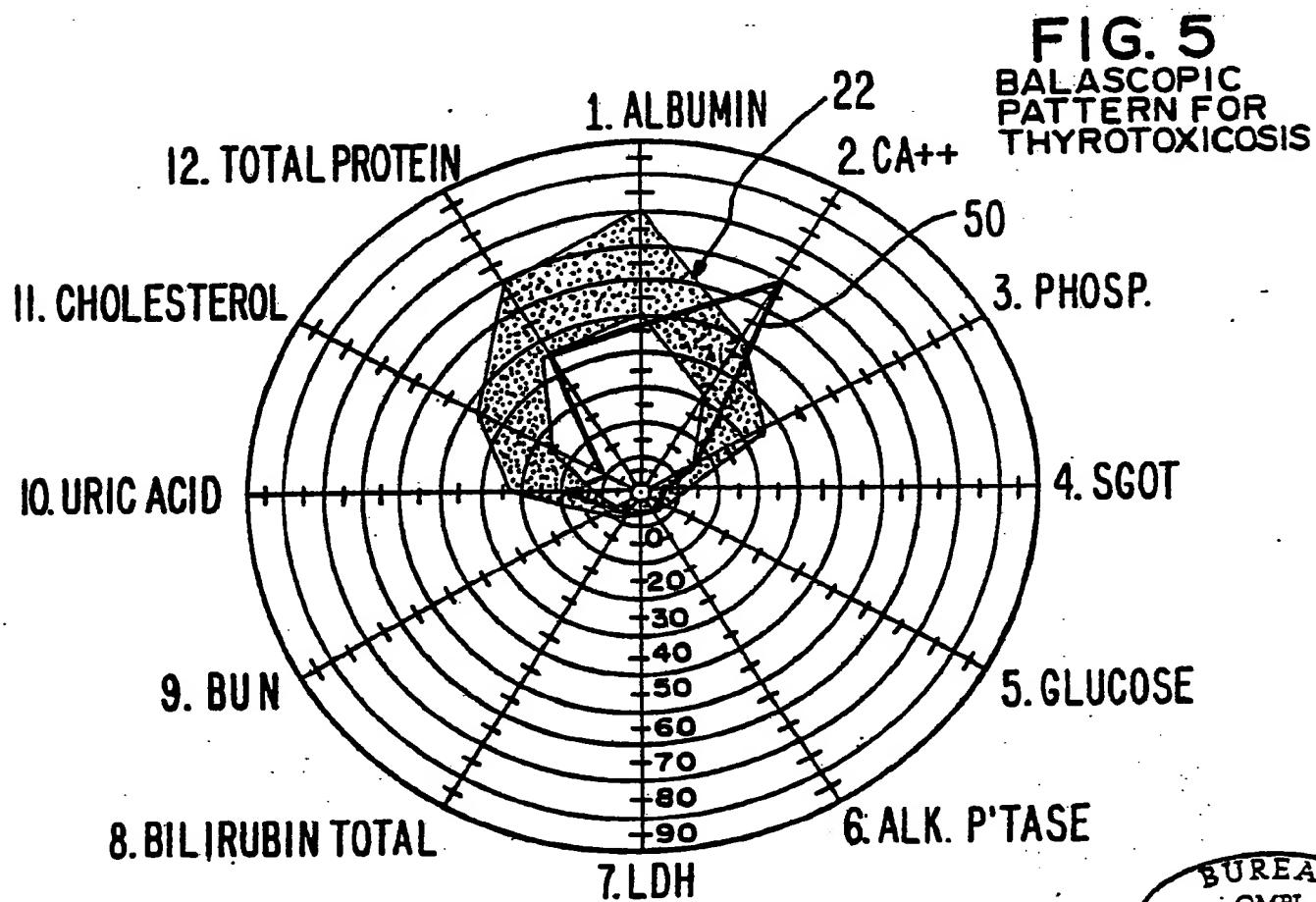
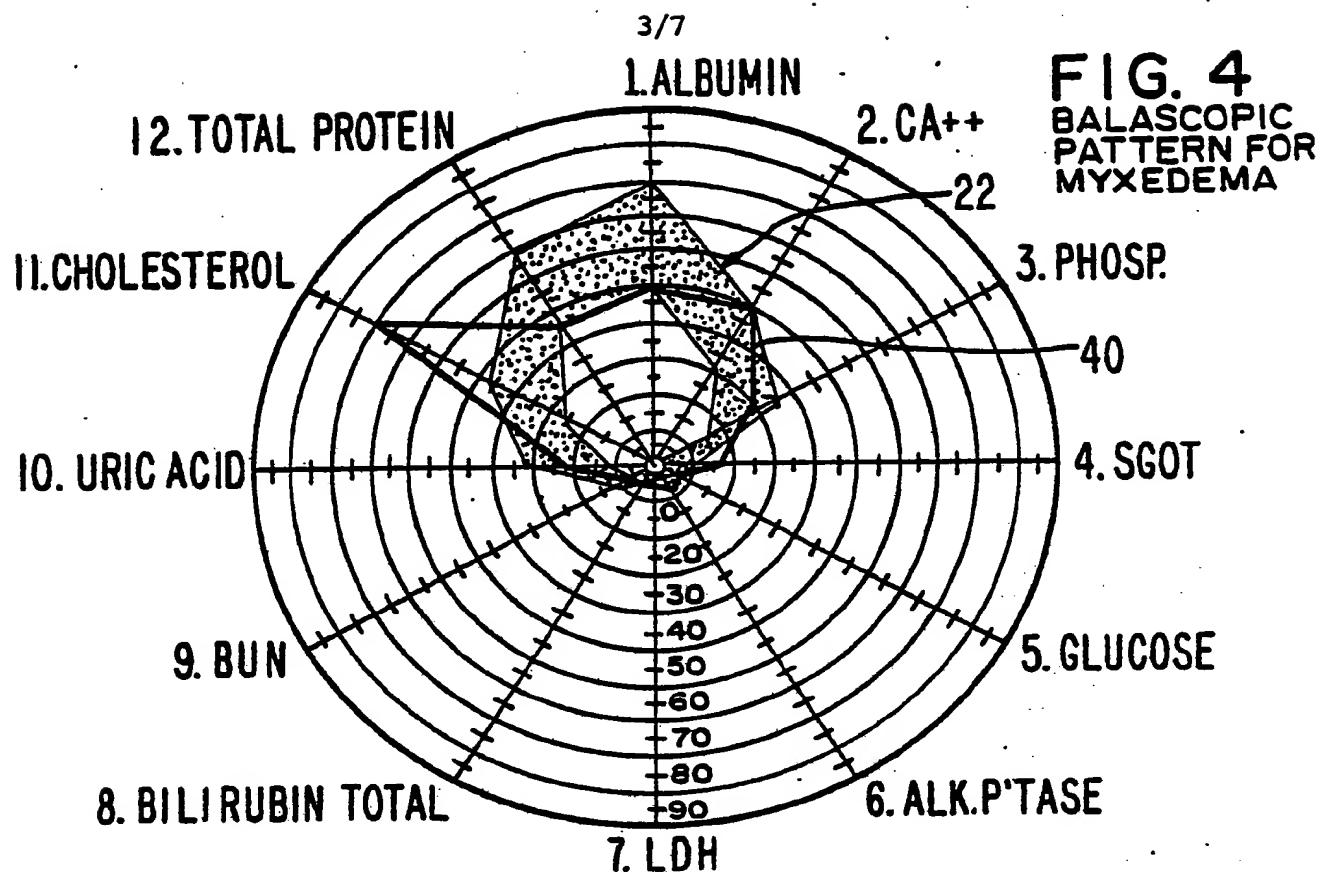


FIG. I
TOTAL SERIUM PROTEIN (P)
AND SERIUM ALBUMIN (A)
LEVEL IN BU





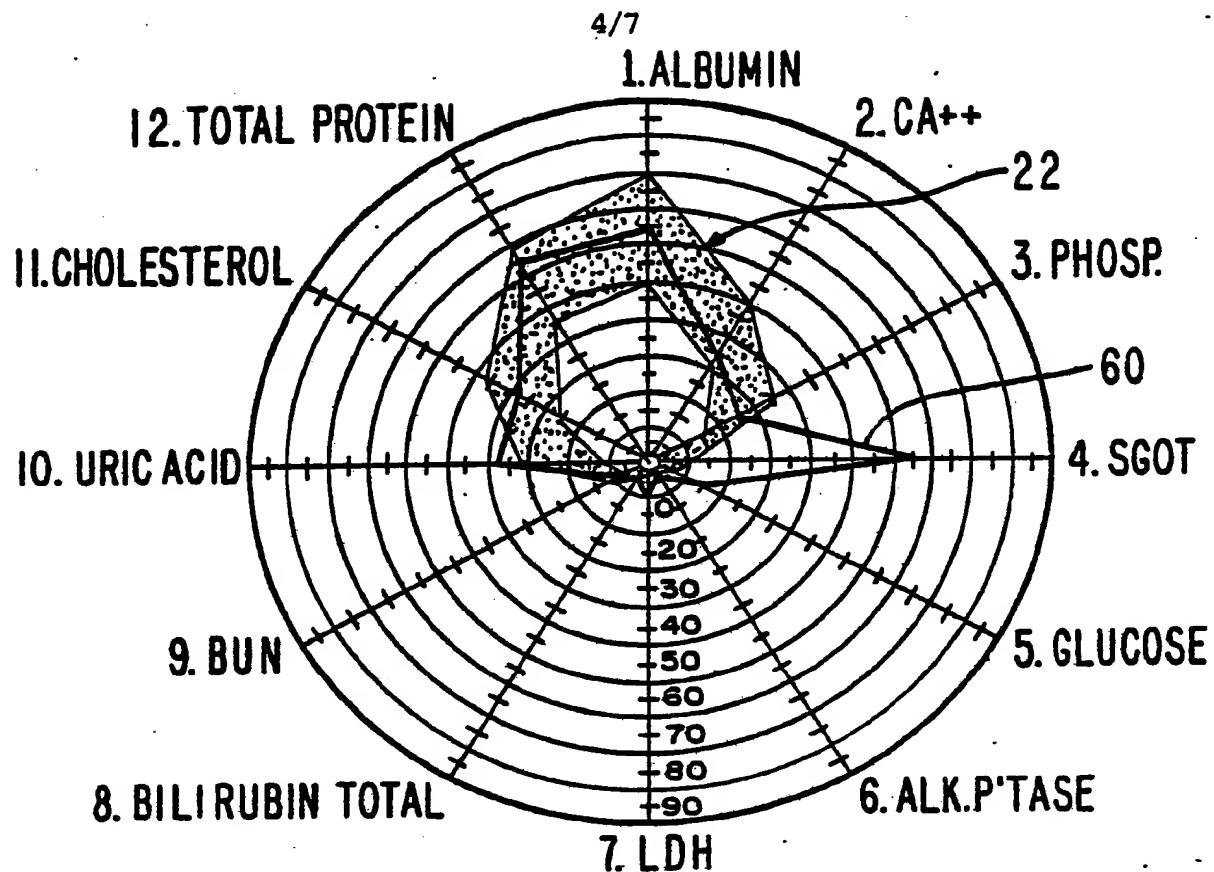


FIG. 6
BALASCOPIC PATTERN FOR
MYOCARDIAL INFARCT (MI)

| BU | 64 | 35 | 26 | 66 | 14 | 6 | 13 | 4 | 9 | 39 | 37 | 57 | PARAMETER |
|-------------------------------|-----------|-----------|-----------|-----------|-----------|----------|----------|-----------|-----------|-----|-----|-----|-----------|
| ACT. VAL. (Mg/dLQR V/l) | 4.2 | 8.8 | 3.6 | 330 | 183 | 84 | 665 | .6 | 15 | 8.4 | 218 | 7.1 | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | |
| | N | N | CI 96% | CN 6% | N | CN 9% | N | N | CN 22% | N | N | | 1 |
| | N | NI | CN 22% | CN 3% | CN 27% | N | N | CI 20% | NI | NI | N | | 2 |
| | FI 12% | N | N | I | N | N | NI | N | N | | | | 3 |
| IMBALANCE | FI 49% | FN | FN 51% | FN 59% | FI 53% | NI | NI | CI 80% | | | | | 4 |
| | FN 3% | N | FN | NI | N | N | N | | | | | | 5 |
| | FN 5% | N | N | FN 4% | N | N | N | | | | | | 6 |
| | FN 4% | NI | N | N | N | N | CN 4% | | | | | | 7 |
| | N | FN 4% | N | N | N | N | N | | | | | | 8 |
| | FN 4% | N | N | N | N | N | N | | | | | | 9 |
| | NI | CN 22% | | | | | | | | | | | 10 |
| | N | | | | | | | | | | | | 11 |

FIG. 7

PARAMETRIC QUALITATIVE
RELATIONSHIPS-
MI OF FIG. 6

LEGEND:

N = NORMAL

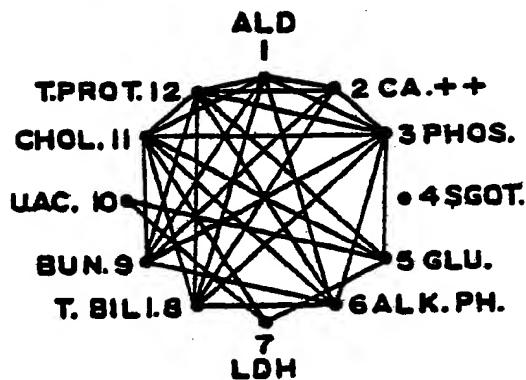
CN = CLOSER THAN NORMAL

FN = FARTHER THAN NORMAL

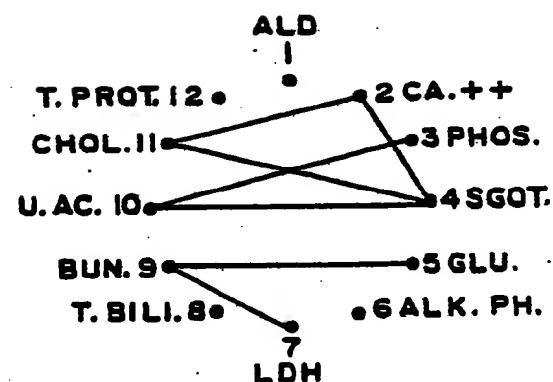
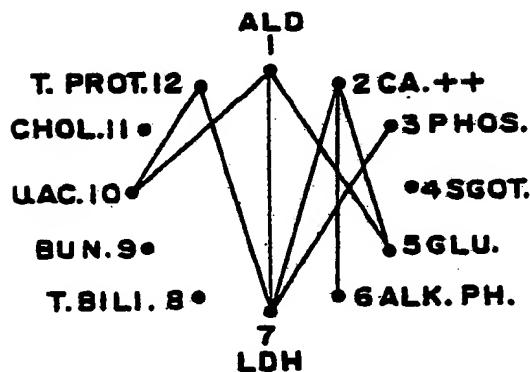
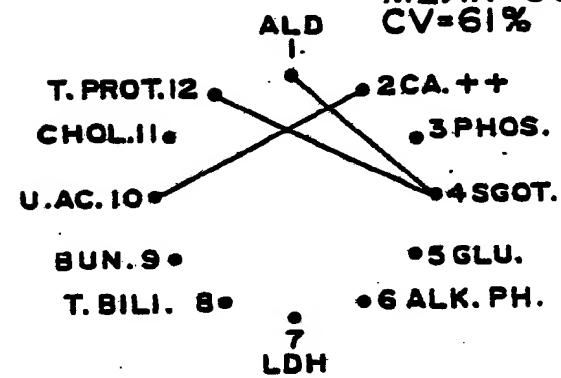
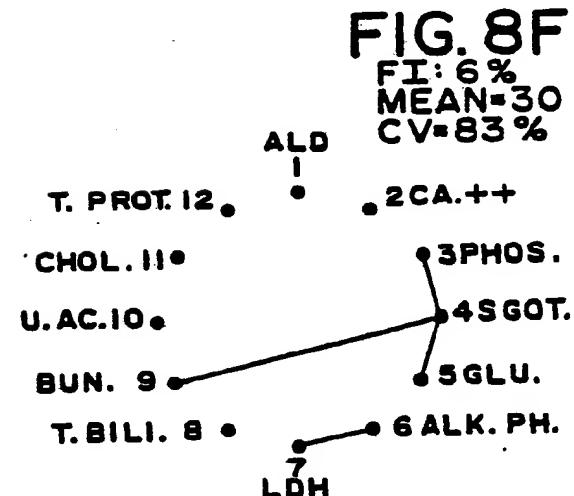
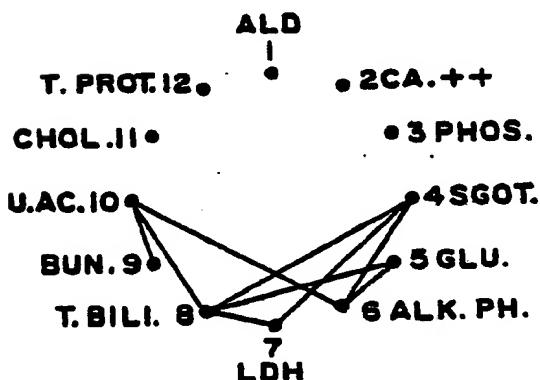
NI = NORMAL & INVERTED

CI = CLOSER & INVERTED

FI = FARTHER & INVERTED

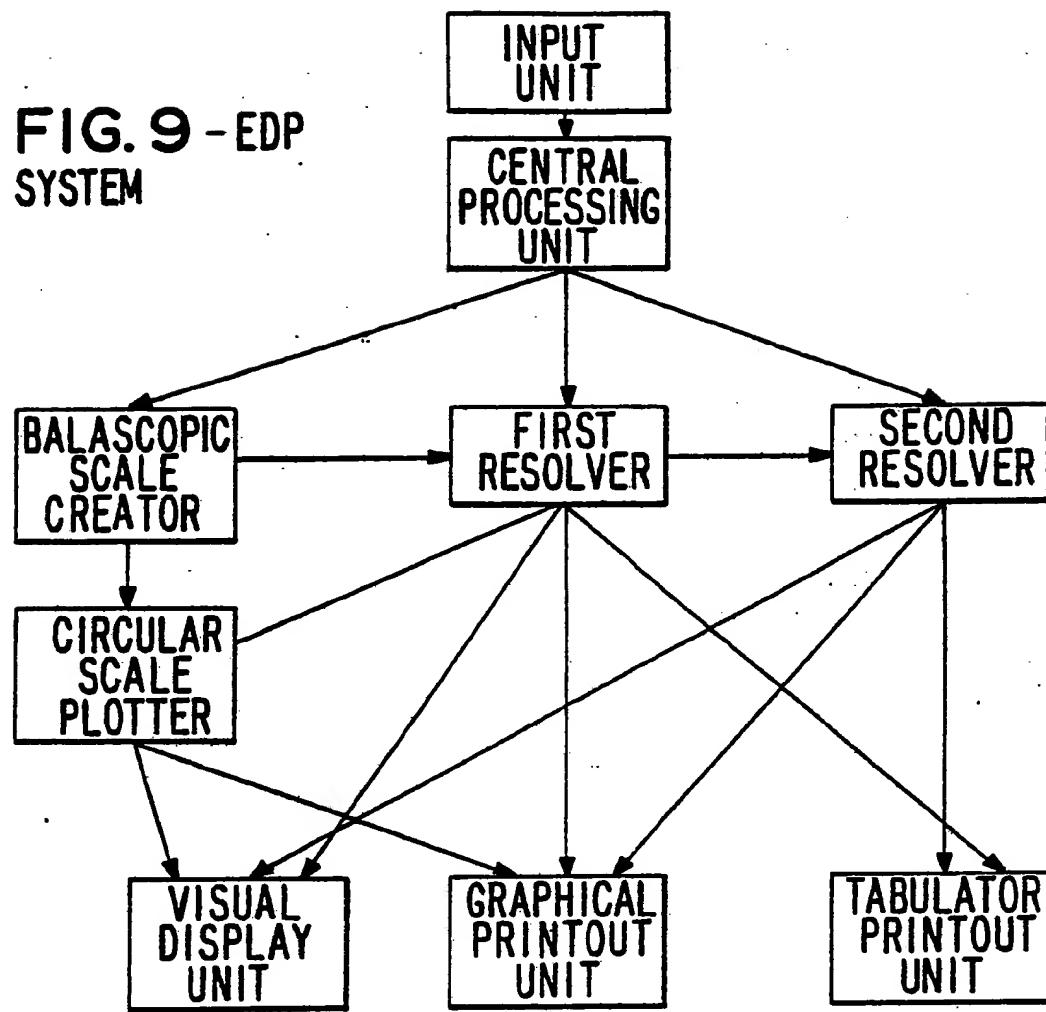
FIG. 8A
N: 50%

6/7

FIG. 8B
N: 12%**FIG. 8C**
CN: 14% MEAN=14 CV=70%**FIG. 8D**
CI: 5%
MEAN=65
CV=61%**FIG. 8E**
FN: 14% MEAN=21 CV=125%**FIG. 8** - CIRCULAR POINT AND LINE PLOTS FOR EACH PARAMETRIC RELATIONSHIP OF MI OF FIG. 6

BUREAU
OMPI
WIPO
INTERNATIONAL

FIG. 9 - EDP
SYSTEM



INTERNATIONAL SEARCH REPORT

International Application No PCT/US83/01730

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ³

According to International Patent Classification (IPC) or to both National Classification and IPC
 INT. CL. 3 A61B 5/04; G06G 7/12
 U.S. CL. 364/582; 128/710; 340/741; 364/415

II. FIELDS SEARCHED

Minimum Documentation Searched ⁴

| Classification System | Classification Symbols |
|-----------------------|---|
| U.S. | 364/413, 415, 416, 518, 550-552, 582 128/630, 709, 710 340/722, 741; 346/33ME |

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched ⁵

III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴

| Category ⁶ | Citation of Document, ¹⁵ with indication, where appropriate, of the relevant passages ¹⁷ | Relevant to Claim No. ¹⁸ |
|-----------------------|--|-------------------------------------|
| A | US, A, 4,093,857, (LAPIDUS) 06 June 1978 | 1,4 |
| A | US, A, 4,027,148, (ROSENTHAL) 31 May 1977 | 1,4 |
| A | US, A, 3,835,839, (BROWN) 17 September 1974 | 1,4 |
| X | US, A, 3,811,040, (WEINFURT ET. AL.) 14 May 1974 | 1,2,4,5 |

* Special categories of cited documents: ¹⁶

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search ⁸

20, January 1984

Date of Mailing of this International Search Report ⁹

27 JAN 1984

International Searching Authority ¹⁰

ISA/US

Signature of Authorized Officer ¹⁰


ERROL A. KRASS